UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/532,585	04/25/2005	Kenshi Kamei	KAMEI2	4282

1444 7590 06/30/2006

BROWDY AND NEIMARK, P.L.L.C.
624 NINTH STREET, NW
SUITE 300
WASHINGTON, DC 20001-5303

EXAMINER	
SPIVACK, PHYLLIS G	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 06/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/532,585	KAMEI ET AL.	
	Examiner	Art Unit	
	Phyllis G. Spivack	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 April 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3-6-06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Applicants' Preliminary Amendment filed April 25, 2005 is acknowledged. Claims 1-20 are presented and represent all of the claims under consideration.

An Information Disclosure Statement filed March 6, 2006 is further acknowledged and has been reviewed.

Claims 4-9 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicants are required to cancel the claims, or amend the claims to place the claims in proper dependent form, or rewrite the claims in independent form. Intended use confers no patentability weight to composition claims. Applicants are not entitled to procure claims based on discovery that known compositions can be adapted to new uses. See *In re Hack*, 114 USPQ 161 (CCPA 1957).

Claims 1-20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention. The claims are directed to treating and/or preventing any defecation dysfunction comprising administering a compound of instant claim 1. The specification provides support for the administration of the compound GM-611 to improve defecation function following morphine administration and to accelerate defecation. The specification fails to provide support for the prevention of defecation dysfunction or for the treatment of any defecation dysfunction other than that subsequent to morphine administration.

Attention is directed to *In re Wands*, 8 USPQ2d 1400 where the court set forth

factors to consider when assessing whether or not a disclosure would require undue experimentation. These factors are:

1) the quantity of experimentation necessary

2) the amount of direction or guidance provided

3) the presence or absence of working examples

4) the nature of the invention

5) the state of the art

6) the relative skill of those in the art

7) the predictability of the art and

8) the breadth of the claims.

The instant specification fails to provide guidance that would allow the skilled artisan background sufficient to practice the instant invention without resorting to undue experimentation in view of further discussion below.

The nature of the invention, state of the prior art, relative skill of those in the art and the predictability of the art

The claimed invention relates to treating and/or preventing any defecation dysfunction comprising administering a compound of instant claim 1. Given their broadest interpretation, the claims are drawn to methods of treating various bowel pathologies as they relate to defecation.

The relative skill of those in the art is generally that of a Ph.D. or M.D. with expertise in the area of gastroenterology.

Each particular type of pathology, symptom or condition that relates to bowel function would reasonably have its own specific characteristics and etiology. The broad recitation "treating and/or preventing defecation dysfunction in a patient" comprising administering a compound of instant claim 1 is inclusive of many conditions that presently have no established successful therapies. For example, according to The Merck Manual, difficulty in defecating may arise from a lack of coordination of pelvic floor muscles and anal sphincter. A successful treatment modality for one particular type of pathology, symptom or condition involved with defecation dysfunction does not presage success for treating another type.

The breadth of the claims

The claims are very broad and inclusive of any condition associated with defecation dysfunction in a subject.

The amount of direction or guidance provided and the presence or absence of working examples

All working examples are limited to the administration of a single compound, GM-611, for treating morphine-induced defecation dysfunction and for acceleration of defecation. No guidance is provided to select another compound encompassed in the formula depicted in instant claim 1. The subject matter encompassed in the language of the instant claims concerning a "preventative" is clearly beyond the scope of the instant disclosure.

The quantity of experimentation necessary

Applicants have failed to provide guidance as to which particular compound would be preferred for treating the various conditions and symptoms associated with defecation dysfunction that are broadly encompassed in the claim language. The means to prevent defecation dysfunction are absent. The skilled artisan would expect the interaction of a particular compound in the treatment of a particular type of defecation dysfunction to be very specific and highly unpredictable absent a clear understanding of the structural and biochemical basis for a therapeutic agent. The instant specification sets forth no such understanding. No direction is provided to distinguish among the various etiologic factors that cause defecation dysfunction. Absent reasonable *a priori* expectations of success for preventing any particular type of defecation dysfunction, one skilled in the gastrointestinal art would have to test extensively many conditions of the bowel to discover which is efficacious. Since each prospective embodiment, as well as future embodiments as the art progresses, would have to be empirically tested, undue experimentation would be required to practice the invention as it is claimed in its current scope. The specification provides inadequate guidance to do otherwise.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Peeters, T.L., Current Opinion in Investigational Drugs(abstract).

Peeters teaches the administration of a composition comprising GM-611, an erythromycin derivative of the formula of instant claim 1. Instant R_1 is isopropyl and instant R_2 is methyl. According to Peeters, GM-611 is used to treat gastric motility disorders. The drug promotes peristalsis in the gastrointestinal tract.

A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties Applicants disclose and claim, i.e., defecation dysfunction, are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached on 10:30 AM-7 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ardin Marschel, may be reached on 591-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Phyllis Spivack

June 23, 2006

Phyllis G. Spivack

PHYLLIS SPIVACK
PRIMARY EXAMINER